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Pharmaxis Ltd. (PXS)

Interim data from Phase 1 LOXL-2 program strengthen partnering prospects

Recommendation
Buy (unchanged)
Price
\$0.315
Valuation
\$0.52 (previously \$0.56)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

Capital growth	65.1%
Dividend yield	0.0%
Total expected return	65.1%

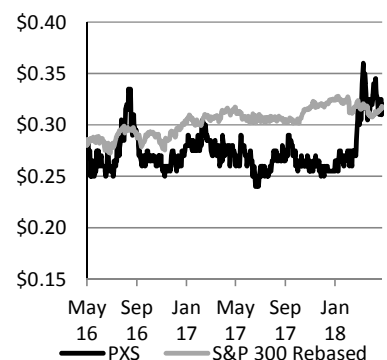
Company Data & Ratios

Enterprise value	\$74.8m
Market cap	\$100.7m
Issued capital	319.8m
Free float	98.1%
Avg. daily val. (52wk)	\$78,857
12 month price range	\$0.2275- \$0.37

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.33	0.27	0.28
Absolute (%)	-1.54	20.75	14.29
Rel market (%)	-4.22	21.52	12.64

Absolute Price



SOURCE: IRESS

Key highlights from 3QFY18

PXS' LOXL-2 asset has successfully completed the single ascending part (SAD) of its Phase 1 program and both the compounds are progressing into the multiple ascending dose (MAD) part of the study, indicating no safety or tolerability issues which is encouraging. Importantly PXS noted that they have seen significant and long lasting inhibition of LOXL-2 that is dose dependent for both compounds in the SAD part of the study. We are highly encouraged by this as dose dependent relation along with no safety issues bodes well for higher inhibition of target in MAD part of the study. In our view, PXS' SAD results also indicate that PXS has the better asset than Pharmakea (given Pharmakea did not show long term inhibition) and this should in turn make it more attractive to potential partners. Results from Phase 2A trials for partnered asset with Boehringer Ingelheim (BI) are now expected in 1HCY19 (was 2HCY18).

Key catalysts approaching in 2HCY18 for LOXL-2 asset

PXS' Phase 1 trial with the LOXL-2 asset is now progressing into the MAD part of the trial, with results expected in 3QCY18. The company is already engaged with multiple companies in discussions around partnering the asset. PXS is also running in parallel 3-month toxicology studies and investing in scaling up manufacturing to GMP standards to make the asset Phase 2 ready for a potential partner. We expect a deal for LOXL-2 should follow close behind results from the ongoing Phase 1 trials and these longer term tox studies and look for a deal to be finalised in 2HCY18.

Valuation reduced to \$0.52, Retain Buy (speculative)

Revisions to our model have resulted in a decrease in our NPAT forecasts for FY18 by -18% driven by higher opex related to the Bronchitol and Aridol segment, partially offset by a decrease in our net loss forecasts for FY19 by -8%, driven by higher risk-adjusted LOXL-2 related upfront and milestone revenues following lift of probability of success assigned to it to 20.0% (vs. 17.5%). Changes to our net loss forecast for FY20 was not material. Our valuation for PXS has reduced to A\$0.52/sh (was A\$0.56/sh), driven by longer term impact of shift in estimated launch timelines for BI drug BI_1467335 from FY26 to FY27. We retain Buy (Spec).

Earnings Forecast

Year end 30th June	2016A	2017A	2018E	2019E	2020E
Revenue (A\$m)	17.8	17.3	50.2	18.2	15.8
EBITDA (A\$m)	-14.8	-15.2	10.2	-6.6	-5.4
NPAT (reported) (A\$m)	-16.5	-18.3	5.9	-10.9	-9.9
NPAT (normalised) (A\$m)	-15.3	-17.4	7.1	-9.7	-8.7
EPS (reported) (cps)	-5.2	-5.7	1.8	-3.4	-3.1
EPS (adjusted) (cps)	-4.8	-5.5	2.2	-3.0	-2.7
EPS growth (%)	N/A	N/A	NM	N/A	N/A
PER (x)	N/A	N/A	14.3	N/A	N/A
EV/EBITDA (x)	-5.0	-4.9	7.3	-11.4	-13.9
Dividend (cps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-73.0%	-494.3%	66.7%	NM	111.9%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE, MILESTONES FROM BI DEAL AND FY19 AND FY20 REVENUE INCLUDES RISK ADJUSTED UPFRONT AND MILESTONES FROM LICENSING DEAL FOR LOXL-2. SOURCE: BELL POTTER SECURITIES ESTIMATES

3QFY18 quarterly update – Key highlights

PXS has provided an update on its various programs for 3QFY18. Key operational highlights are as follows:

- PXS' received the a €10m (~A\$15.2m) milestone payment from partner Boehringer Ingelheim (BI) which was triggered on the first patient being dosed in the Phase 2A trial for Diabetic Retinopathy (DR) with the SSAO/VAP-1 inhibitor BI_1467335.
- Boehringer Ingelheim has recently updated timelines for completion of the Phase 2A trials ongoing for BI_1467335 for both NASH and DR. Results from the NASH trial are now expected in 2QCY19 (vs. 3QCY18) and from the DR trial also in 2QCY19 (vs. 4QCY18). This has moved are estimated timelines for receipt of milestones, approval and launch of this drug for both the indications.
- The company's LOXL-2 asset has successfully completed the single ascending part (SAD) of its Phase 1 program and both the compounds are progressing into the multiple ascending dose (MAD) part of the study. Positive ethics approval to proceed indicate there were no safety or tolerability issues which is encouraging. Importantly PXS noted that they have seen significant and long lasting inhibition of LOXL-2 that is dose dependent for both compounds in the SAD part of the study i.e. good evidence of target engagement seen. This was observed using PXS' proprietary target engagement assay which is sensitive enough to measure LOXL-2 in healthy volunteers. **We are highly encouraged by this as dose dependent relation along with no safety issues bodes well for higher inhibition of target in MAD part of the study.** We also note that recently PXS' peer Pharmakea who also has a LOXL-2 in the clinic noted that they saw good evidence of target engagement at 2 hours at all doses in the SAD part of their study, however the inhibition was not long lasting and waned materially at 24 hours for all 3 doses. **In our view, therefore PXS' SAD results so far indicate that PXS has the better asset and this should in turn make it more attractive to potential partners.**
- PXS has also initiated longer term (3 months) tox studies for LOXL-2 asset which should also complete in 3QCY18 and also started investing in scaling up manufacture, which should further add value to the licensing package making the drugs more Phase 2 ready for a potential partner. The company is targeting partnering the asset following results from both the Phase 1 trial and the longer term tox studies being available in 3QCY18.
- Other pipeline programs LOX and SSAO/MPO have also progressed. Lead candidates have been identified for both and the company has initiated formal toxicology studies for both with the aim to make them Phase 1 ready by end CY18 and enter the clinic in FY19. The company is focused on identifying the appropriate indications to pursue for both.
- Submission by partner Chiesi for Bronchitol to the US FDA is now expected in early 4QCY18 (vs. 3QCY18). The submission will include all the 3 Phase 3 studies of Bronchitol and we understand Chiesi is investing significantly in putting the submission together which has led to the slight delay in timelines. On US launch PXS stands to get US\$10m in milestone and mid to high teen royalties on net sales. PXS will also supply the product to Chiesi.
- Sales for Bronchitol were particularly strong in both Western Europe and Australia over pcp and sequential quarter. Quarterly sales over pcp were impacted by no order from Russia in this quarter vs. an initial order in the pcp period. PXS has filed an application for national reimbursement in Russia for which a decision is expected in 2HCY18. The company also expects to receive an order from Russia in 2HCY18.

- Sales of Aridol were down in the quarter over pcp impacted by lower sales to South Korea. Sales in both Australia and EU markets showed slight increases as expected.
- PXS along with its distributor Metapharm Inc has made an FDA submission to get its manufacturing facility approved. They expect approval by end of CY18 which should allow them to launch in the US. The company also expects to file for approval of the product in Canada in 2QCY18. Review time in Canada is expected to take around 12 months, with potential launch of the product in Canada in FY20.
- Current cash reserves are A\$34.5m, borrowings were A\$8.5m, which leaves PXS with a net cash position of A\$26.0m. This provides runway through CY19, with further boost expected through a licensing deal for LOXL-2 asset in 2HCY18.

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on its quarterly update for 3QFY18 filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- We have increased the probability of success assigned to LOXL-2 from 17.5% to 20.0%, following update by company that they have finished the single ascending part of the ongoing Phase 1 program, received ethics approval to progress to the multiple ascending part (i.e. no safety issues identified) and have seen significant and long lasting inhibition of LOXL-2 that is dose dependent for both compounds i.e. good evidence of target engagement seen. This has led to an increase in our risk adjusted upfront and milestone revenue from the LOXL-2 deal for FY19 and FY20.
- We have shifted our launch timelines for the PXS/BI drug BI_1467335 from FY26 to FY27, following the revised timelines for completion of ongoing Phase 2A trials in both NASH and Diabetic Retinopathy (DR) to 1HCY19 (vs. previous 2HCY18). We now expect results from both these trials in 2QCY19. Accordingly we have also moved the timelines for receipt of future milestones from Boehringer Ingelheim.
- For FY18 we have reduced our drug development costs for the pipeline assets LOX and SSAO/MPO assets and increased our FY19 costs by the same amount, based on the expense related to these in the first 9 months of FY18.
- For FY18 we have increased our clinical costs related to the LOXL-2 program and decreased our FY19 costs by same amount, with some of the costs being brought forward to FY18.
- We have slightly reduced (by ~\$0.1m) Aridol sales from South Korea for FY18 based on reported 3QFY18 number, which was offset by ~\$0.1m increase in our new drug development revenues due to the slightly higher than expected milestone revenue received from partner BI this quarter in AUD terms.
- We have increased our other expenses for the Bronchitol and Aridol segment to \$0.4m from FY18 onwards (vs. gain of \$0.1m estimated earlier) based on 3QFY18 reported numbers.
- We have rolled forward our DCF model for the quarter.

The net result is a decrease in our NPAT forecasts for FY18 by -18% driven by higher opex related primarily to the Bronchitol and Aridol segment, partially offset by a decrease in our net loss forecasts for FY19 by -8%, driven by higher risk-adjusted LOXL-2 related upfront and milestone revenues following lift of probability of success assigned to it to 20.0% (vs. 17.5%). Changes to our net loss forecast for FY20 was not material. Our valuation for PXS has reduced to A\$0.52/sh (was A\$0.56/sh), primarily driven by longer term impact of the shift in estimated launch timelines for PXS/BI drug BI_1467335 from FY26 to FY27. **We retain our Buy (Speculative) recommendation.**

**We value PXS at
\$0.52/sh**

Table 1 - Key Changes to our FY18-20 Forecasts

	FY2018E			FY2019E			FY2020E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	50.2	50.2	0%	16.9	18.2	8%	14.9	15.8	6%
Interest Income	0.6	0.6	-4%	0.6	0.6	-5%	0.4	0.4	-3%
Operating Costs	39.1	40.1	2%	24.4	24.8	1%	20.2	21.2	5%
EBITDA	11.1	10.2	-8%	-7.5	-6.6	-13%	-5.3	-5.4	2%
EBIT	8.0	7.1	-11%	-10.7	-9.8	-9%	-8.5	-8.6	1%
NPAT (adjusted)	8.3	7.1	-15%	-10.6	-9.7	-9%	-8.6	-8.7	1%
Adjusted Diluted EPS	2.6	2.2	-15%	-3.3	-3.0	-9%	-2.7	-2.7	1%
NPAT (reported)	7.1	5.9	-18%	-11.8	-10.9	-8%	-9.8	-9.9	1%
Reported Diluted EPS	2.2	1.8	-18%	-3.7	-3.4	-8%	-3.1	-3.1	1%

ALL AMOUNTS IN AUD IN MILLIONS EXCEPT EPS. SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation model is based on a WACC of 16.0% and a terminal growth rate of 1%.

Table 2 - Summary of Valuation

Forecasts	Base case
Enterprise value from DCF (AUDm)	147.3
Add: Reported Cash (AUDm)	34.5
Less: Current Debt	8.5
Equity value (AUDm)	173.3
Total diluted shares (million)	333.5
Value per share (AUD)	\$0.52
Current Share price (AUD)	\$0.32
Expected Capital Growth	65.1%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 3 - PXS Sum-of-parts DCF Valuation Summary

Asset	Probability adjusted NPV (A\$m)	Value per share (A\$)	% Mix	Probability of success/Risk adjustment	Current Phase
Bronchitol and Aridol	(\$18)	-\$0.05	-10.5%	Aridol - Canada (60%)	Marketed (Ex -US and Canada)
New Drug Development	\$207	\$0.62	119.8%	BI_1467335 (NASH, DR - 23.5%), LOXL-2 (NASH -20.0%)	BI_1467335 (Phase 2A) and LOXL-2 (Phase 1)
Corporate/Non-Allocated	(\$42)	-\$0.13	-24.2%	NA	NA
Reported Cash	\$35	\$0.10	19.9%	NA	NA
Reported Debt	(\$9)	-\$0.03	-4.9%	NA	NA
Equity Value	\$173.3	\$0.52	100.0%		

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 4 – PXS- Key assumptions used in New Drug Development segment

Asset	Indication	Stage	Partnering Status	First Fiscal Year of sales (Est.)	Peak Market share	Peak Global Sales (US\$m)	Probability of success
BI_1467335	NASH - F2/F3 fibrosis stage	Phase 2A	Boehringer Ingelheim	2027	5% (US), (3.5% ROW)	\$1,962	23.5%
BI_1467335	Diabetic Retinopathy (DR)	Phase 2A	Boehringer Ingelheim	2027	10.0%	\$813	23.5%
LOXL-2	NASH - F3/F4 fibrosis stage	Phase 1	Will look to partner	2028	5% (US), (3.5% ROW)	\$1,448	20.0%

GLOBAL PEAK SALES ARE PRE-RISK ADJUSTMENT AND ROYALTIES. SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 5 – Deal Assumptions for Key Drug Development Pipeline Assets

Asset	Indication	Stage at Licensing	Licensee	Fiscal Year Timing of deal (Est.)	Total Deal Value in USDm (upfront plus milestones)	Upfront (USDm)	Other developmental & regulatory Milestones (USDm)	Commercial Milestones Est (USDm)	Royalty Rate (%)	PXS's share
BI_1467335	NASH and Diabetic Retinopathy	Phase 1	Boehringer Ingelheim	2015	645	33	462	150	11.0%	100.0%
LOXL-2	NASH and a second indication (potentially IPF)	Phase 1 complete	TBC	2019	700	50	470	180	11.0%	83.0%

NOTE: ROYALTIES ARE LIKELY TO BE TIERED. WE ASSUME A FLAT RATE FOR NOW. FOR LOXL-2 DEAL PXS AND ITS PARTNER SYNIRGEN WILL SHARE THE DEAL VALUE IN 83:17 RATIO. THE BI DEAL VALUE INCLUDES OUR ESTIMATES ABOUT POTENTIAL UNDISCLOSED COMMERCIAL MILESTONES WHICH ARE PART OF THE DEAL AND HENCE MAY BE CONSERVATIVE. THE BI DEAL IS IN EUROS, WE HAVE CONVERTED IT TO USD AT CURRENT EXCHANGE RATES. SOURCE: BELL POTTER SECURITIES ESTIMATES

Upside Risk to our valuation

- **Clinical success will allow for increased probability of success:** We currently assign a 23.5% probability of success (of reaching the market) to BI_1467335, given that it's currently in a Phase 2A trial, for both NASH and DR. We envisage that completion of the trial with positive results and subsequent advancement of BI_1467335 into Phase 2B trials (BPe 2HCY19) will allow us to assign a higher probability of success and therefore will lead to material upgrades in our numbers.

Similarly, we currently assign a 20.0% probability of success (of reaching the market) to LOXL-2 in NASH, given that it's currently in a Phase 1 trial with interim data from the single ascending part of the trial indicating target engagement. We envisage that completion of Phase 1 with positive results and subsequent advancement of LOXL-2 into Phase 2A trials will allow us to assign a higher probability of success and therefore will lead to material upgrades in our numbers.

- **Timing assumption for licensing deal for LOXL-2:** We currently assume a licensing deal for LOXL-2 in 2HCY18, on completion of its Phase 1 trial and long term toxicology studies. If it gets licensed prior to our estimates, it will be an upside to our valuation.
- **Conservative assumptions for BI_1467335 in absence of Phase 2 clinical data:** Our market penetration & pricing assumptions, are all based on the premise that BI_1467335 will be behind a few years to other NASH approaches such as Allergan's CCR2/CCR5 antagonist and Gilead's selonsertib. Our base assumption at this stage is that BI_1467335 shows at least equivalent efficacy to these assets, with a better safety profile, with the advantage potentially to be used both as a monotherapy and in combination, in the moderate-severe fibrosis stage NASH population, with one or more approved assets by that stage. In the absence of Phase 2 clinical data we are conservative in our assumptions at this stage.
- **Conservative assumptions for LOXL-2 to start with in absence of clinical data:** Our market penetration & pricing assumptions and deal size assumptions, are all based on the premise that LOXL-2 will be behind several years to other drugs targeting NASH to get to market. At that stage we expect the drug is more likely than not to be used as an add on therapy with existing standard of care by then to improve efficacy, likely in the more severe end of the fibrosis stage spectrum of NASH. However, given the scarcity of anti-fibrotic assets in development for NASH, we expect both partnering interest and deal size for the LOXL-2 asset with its novel mechanism of action (MoA) to be in line with other high value deals in this space recently. In the absence of clinical data from LOXL-2 we are conservative in our assumptions at this stage including our assumptions for the deal size. Positive Phase 1 data and interest by multiple pharma parties could lead to a deal higher than our current forecast.
- **We do not model royalty revenue from a second indication (likely IPF) for LOXL-2 presently:** At this stage in our valuation, we do not include a market revenue model for LOXL-2 for Idiopathic Pulmonary Fibrosis (IPF) as a potential secondary indication and therefore do not model royalty revenue as a percentage of net sales from this indication to PXS. Confirmation of IPF as a second indication by PXS' future partner and progress of this into Phase 2 clinical trials is likely to considerably increase the market opportunity for this asset, in which case it's likely to be a source of considerable upside to our valuation in future.
- **No sales milestones from LOXL-2 deal included in our model:** At this stage we do not model PXS' share of the assumed US\$180m sales milestones from a potential LOXL-2 deal in our model. We intend to include it in our model once a LOXL-2 deal is inked by PXS, in which case it's likely to be a source of upside to our valuation.
- **No value assigned for other early stage pipeline assets:** We also do not include any value for PXS' other early stage assets namely SSAO/MPO inhibitor and LOX inhibitor.

Formal toxicology studies for these two assets have now commenced, with the view to moving to the clinic (Phase 1 human trials) in FY19.

The SSAO/MPO program is developing a dual inhibitor of both SSAO and myeloperoxidase (MPO), which has potential anti-inflammatory application in both respiratory and cardiovascular disease. PXS has identified the lead asset and is currently focused on identifying the appropriate indications to pursue.

The LOX inhibitor program is developing a drug which broadly inhibits all the LOX family of enzymes, which has potential anti-fibrotic application in scarring (a topical formulation) and other severe fibrotic indications including some cancers (likely oral formulation). PXS has identified the lead asset and is currently focused on identifying the appropriate indications to pursue.

PXS believes that the above two assets may have higher potential and value add if developed to Phase 2A or 2B before partnering, vs. the strategy with its later stage assets targeting NASH which it looked to partner at or after Phase 1. Progress of these two assets into the clinic in future is likely to be a source of upside to our valuation.

- **We model limited markets for Bronchitol and do not model US market as yet:** For Bronchitol, we model the existing markets of Australia, Western Europe including Italy, Eastern Europe and Russia. We do not model the US market for Bronchitol as yet. PXS' US partner Chiesi is responsible for completing and finalising a New Drug Application (NDA) with the US FDA and subsequent commercialisation of it. Should Bronchitol get approved and launch in US, PXS will receive a US\$10m milestone from Chiesi, additional US\$15m sales milestones and a mid to high teen percentage of royalties on net sales. FDA approval and launch of Bronchitol in the US therefore will be an upside to our valuation for PXS.
- **We model limited markets for Aridol and do not model US market as yet:** For Aridol, we model the existing markets of Australia, Europe and South Korea. We also model revenue from Canada (assigning it a 60% probability of success), given Aridol is not approved in Canada as yet, and filing for approval is expected in 2QCY18. We note we assume a FY20 launch in Canada, given PXS estimates a 12 month review process from filing. We do not model the US market for Aridol as yet. PXS has appointed a distributor for the US and plans to launch subsequent to FDA approval of its Sydney manufacturing facility in FY19.
- **Limited contribution from Bronchitol and Aridol segment in our valuation:** We note that PXS believes the Bronchitol and Aridol segment could transition to profitability over the next 1-2 years, irrespective of any US approval. On our estimates we expect the EBITDA loss from the segment to significantly come down from the FY16/FY17 levels starting FY18, however we do not see the segment becoming profitable out to several more years, continuing instead to make a modest loss, albeit declining each year as product sales pick up. We believe Russia for Bronchitol and Canada for Aridol may surprise us on the upside, however at this stage we choose to be conservative till we see increasing traction in Russia for Bronchitol on obtaining reimbursement and launch in Canada for Aridol.

Pharmaxis Ltd. (PXS)

COMPANY DESCRIPTION

Pharmaxis, is a biopharmaceutical company focused on the development of drugs for inflammatory and fibrotic diseases. Its lead assets Phase 2 SSAO/VAP-1 inhibitor BI_1467335 partnered in a multi-million dollar deal with Boehringer Ingelheim and currently unpartnered Phase 1 LOXL-2 inhibitors are targeting Non-alcoholic Steatohepatitis (NASH), a multibillion dollar market, estimated to grow to be ~US\$20bn-US\$35bn. The drugs while not first-in-class, have the potential to be best-in-class and be useful in other fibrotic diseases and we forecast both to be blockbusters (i.e. have over US\$1bn in peak sales). NASH market is expected to grow with rise in obesity and surpass HCV as the leading cause of liver transplant by 2020. There are currently no approved drugs which make the market largely untapped and underserved. The multifactorial aspect of NASH and future treatments likely to be a combination of therapies ensures that companies remain on the lookout for promising assets to license, which bodes well for licensing prospects for PXS' LOXL-2 inhibitors. PXS also has two marketed respiratory products Bronchitol and Aridol which we view as non-core, however they represent an existing albeit small revenue stream for PXS with potential upside should US approval come through.

INVESTMENT STRATEGY

We have a Buy (speculative) recommendation on Pharmaxis. Our investment thesis is based on:

\$0.52 valuation: We value PXS using a risk adjusted DCF at \$0.52. The valuation is approximately a 65.1% premium to the current share price of \$0.315/sh.

Lead assets targeting NASH have blockbuster potential: Pharmaxis' lead assets Phase 2 SSAO/VAP-1 inhibitor BI_1467335 and Phase 1 LOXL-2 inhibitor are both targeting Non-alcoholic Steatohepatitis (NASH), a multibillion dollar market, estimated to grow to be ~US\$20bn-US\$35bn. We model US\$1.96bn peak worldwide sales (pre risk adjustment) for BI_1467335 in NASH and US\$1.45bn for LOXL-2 in NASH.

NASH represents significant commercial opportunity: NASH is a large market, growing rapidly with an increasing obese population. It is estimated that NASH will surpass Hepatitis C Virus (HCV) as the leading cause of liver transplants by 2020. There are currently no drugs approved for NASH, which makes this market largely untapped and underserved and a lucrative market opportunity for PXS to target. There are several drugs in development and interest and competition has both heated up. There have been a number of high value deals in this space recently and active companies are looking to license or acquire to build a portfolio of assets targeting different stages of NASH. Average deal sizes are around US\$860m, however some deals recently have been over \$1bn.

PXS emerging as a key player in NASH: Drugs targeting NASH in development fall under 3 groups based on their mechanism of action and stage of NASH they target – metabolic modifiers, anti-inflammatory agents and anti-fibrotic agents. It is expected that the future treatment for NASH is likely to be a cocktail of therapies as was seen earlier with HCV. Therefore we see drugs from each of the 3 categories to complement each other and competition likely to be restricted to drugs within the same category. Pharmaxis has two assets which fall under two different categories. BI_1467335 is an anti-inflammatory agent and LOXL-2 asset is an anti-fibrotic agent and therefore should complement each other and other drugs in advanced development. There are very few drugs in development in these 2 categories and as far as we are aware both these drugs are currently the only one in their class being actively developed for NASH.

Drugs not first-in-class but potentially best-in-class: PXS' SSAO/VAP-1 and LOXL-2 inhibitor are not the first in their class. However based on pre-clinical data for both and Phase 1 data for the SSAO drug, we believe the drugs possess a more favourable PK/PD

profile which could make them best-in-class. Data so far provides evidence of good safety profile, good oral bioavailability and potent, long lasting inhibition of targeted enzyme.

Potential exists to expand the use of lead drugs beyond NASH: Both the lead drugs have potential to be used across fibrotic diseases with the SSAO inhibitor in a phase 2 trial for Diabetic Retinopathy (DR) and LOXL-2 being explored in Pulmonary Fibrosis.

Partnership with Boehringer Ingelheim validates chemistry platform: PXS signed a multi-million dollar product acquisition deal with Boehringer Ingelheim (BI) in 2015, which marked the start of the turnaround for the company, strengthened its balance sheet and validated its amine oxidase chemistry platform and its ability to execute valuable deals.

Value inflexion points approaching: Results from both phase 2A trials for the SSAO/VAP-1 drug partnered with BI are expected in 1H CY19. LOXL-2 is in Phase 1, with results due in mid-CY18, with a multi-million dollar licensing deal expected in 2H CY18.

Strong cash position: PXS' current cash position is A\$34.5m. In our view, this provides at least 18 months cash runway, with flexibility to defer some expenses on other pipeline programs to further extend this runway. PXS is unlikely to require any capital raisings in the medium term and we believe the company is well placed to look at capital management initiatives such as a share buyback or special dividend to return some surplus capital to its shareholders after they finalise a deal for LOXL-2 later this year. PXS' strong cash position will also allow it to pursue some asset acquisitions to further enrich its drug development pipeline and also allow the company to consider Phase 2A/2B development for some of its pipeline assets to add more value before partnering them out.

Risks

The key risks specific to Pharmaxis include, but are not limited to, the following:

- **Clinical risk:** There is a risk that PXS' clinical trials for LOXL-2 fail to reach their endpoints, which would in turn impact its partnering prospects.
- **Timing and clinical risk on partnered product:** For its partnered product BI_1467335, PXS is reliant on Boehringer Ingelheim (BI) for development timelines. The ability of PXS' product to finally reach the market and translate into royalty revenue streams for it depends on BI. Delays in timelines will affect near term milestone payments to PXS as well as its long-term revenue flow. Also if the product fails at any stage of clinical development or BI decides to discontinue the development of the product PXS' ability to generate revenue from that asset will diminish/or fail totally.
- **Reliance on partnerships to unlock value:** The success of PXS' business model is underpinned by its ability to ultimately attract valuable partnering deals for its assets, given PXS lacks the commercial infrastructure to support commercialisation. Our valuation in part is underpinned by PXS' ability to ultimately attract a valuable partnering deal for its LOXL-2 asset. Failure to attract partners for this asset or to negotiate attractive deal terms as we have postulated will impact our forecasts.
- **Bronchitol US approval decision may have sentiment impact, although won't affect our valuation:** The revenue driver in our model for PXS is its 'New Drug Development segment' which includes the partnered BI_1467335 drug for the indication NASH and Diabetic Retinopathy and its currently unpartnered asset LOXL-2 also targeting NASH and other fibrotic indications. While we look at Bronchitol and Aridol, PXS' currently marketed products as non-core assets and attribute minimal value to it, with no value in our model for Bronchitol's potential US approval and launch, we believe PXS is vulnerable to partner Chiesi's success/failure in obtaining US regulatory approval for Bronchitol, which could impact sentiment around the company.
- **Regulatory risk:** Successful commercialisation of PXS' products is ultimately dependent on getting approval from the regulatory authorities to commercially launch the product. While PXS' partner with much more experience in navigating regulatory channels will be responsible for obtaining approvals, failure to satisfy regulatory requirements could mean that the product will fail to reach the market.
- **Commercial risk:** The pharmaceutical market is intensely competitive and in particular the NASH space which PXS is targeting has several companies engaged in drug development. PXS' products are unlikely to be the first to market and therefore would not have first mover advantage. There is no guarantee that mid-late stage clinical trial results of the BI drug or the LOXL-2 drug, even if they hit the endpoints of the studies, will be viewed as clinically meaningful by clinicians' vis-à-vis other approved NASH drugs by then on the market. Even if the drugs do get approved on successful pivotal studies, commercial adoption might still be hampered by the cost of the combination (especially in LOXL-2's case where we assume an add-on therapy positioning) or the competition in the NASH market having much larger impact than we have postulated.
- **Funding risk:** Delays in partnering of LOXL-2 may impact PXS' funding position in the long term. PXS has A\$34.5m in cash and debt related to finance lease of A\$8.5m, amounting to a net cash position of A\$26.0m. Although PXS has a high cash balance currently, which should provide cash runway through CY19, the company may need to raise additional capital for funding its requirements beyond that should there be delays in partnering its LOXL-2 asset. There is no guarantee that PXS will be able to secure additional financing if and when required.

Table 6 - Financial summary

Pharmaxis Ltd (PXS)						Share price (A\$)	\$0.315														
As at 30 April 2018						Market cap (A\$)	100.7														
Profit and Loss						Valuation data															
Y/e June 30 (A\$m)	2016A	2017A	2018E	2019E	2020E	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Product Sales Revenues	6.1	4.8	6.1	6.8	7.3	Net profit - normalised (A\$m)	-15.3	-17.4	7.1	-9.7	-8.7										
Other Revenue (commercial)	8.2	8.6	43.5	10.8	7.9	EPS - normalised (c)	-4.8	-5.5	2.2	-3.0	-2.7										
Other Income	3.5	3.9	0.6	0.6	0.6	EPS growth (%)	N/A	N/A	NM	N/A	N/A										
Total Revenue	17.8	17.3	50.2	18.2	15.8	P/E ratio (x)	N/A	N/A	14.3	N/A	N/A										
EBITDA	-14.8	-15.2	10.2	-6.6	-5.4	FCFPS (c)	-4.2	-5.0	2.7	-1.9	-1.9										
Depreciation & Amortisation	-3.0	-3.1	-3.1	-3.2	-3.2	Price/FCF (x)	-7.5	-6.3	11.5	-16.3	-16.3										
EBIT	-17.9	-18.3	7.1	-9.8	-8.6	DPS (c)	0.0	0.0	0.0	0.0	0.0										
Net interest & Other Income/(Expense)	2.6	0.9	0.0	0.1	0.0	Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%										
Pre-tax profit	-15.3	-17.4	7.1	-9.7	-8.7	Franking (%)	N/A	N/A	N/A	N/A	N/A										
Tax	0.0	0.0	0.0	0.0	0.0	EV/EBITDA	-5.0	-4.9	7.3	-11.4	-13.9										
Net profit (loss) normalised	-15.3	-17.4	7.1	-9.7	-8.7	EV/EBIT	-4.2	-4.1	10.6	-7.7	-8.7										
Abnormal items	-1.2	-0.9	-1.2	-1.2	-1.2																
Reported Net profit (loss)	-16.5	-18.3	5.9	-10.9	-9.9																
Cashflow						<table border="1"> <tr> <td>Share price now (A\$)</td> <td>\$0.315</td> </tr> <tr> <td>Valuation (A\$):</td> <td>\$0.52</td> </tr> <tr> <td>Premium (discount) to price</td> <td>65.1%</td> </tr> <tr> <td>Recommendation:</td> <td>Buy</td> </tr> <tr> <td>Risk Rating</td> <td>Speculative</td> </tr> </table>						Share price now (A\$)	\$0.315	Valuation (A\$):	\$0.52	Premium (discount) to price	65.1%	Recommendation:	Buy	Risk Rating	Speculative
Share price now (A\$)	\$0.315																				
Valuation (A\$):	\$0.52																				
Premium (discount) to price	65.1%																				
Recommendation:	Buy																				
Risk Rating	Speculative																				
Y/e June 30 (A\$m)	2016A	2017A	2018E	2019E	2020E	Profitability ratios															
Reported NPAT	-16.5	-18.3	5.9	-10.9	-9.9	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Non-cash items	2.6	3.7	4.9	4.9	4.8	EBITDA margin (%)	N/A	N/A	20.3%	N/A	N/A										
Net change in Working capital	1.8	-0.6	-1.0	1.0	0.0	EBIT margin (%)	N/A	N/A	14.1%	N/A	N/A										
Operating cashflow	-12.0	-15.3	9.7	-5.0	-5.0	Return on assets (%)	-23.3%	-38.3%	15.0%	-26.2%	-32.5%										
Capex	-1.4	-0.3	-0.8	-0.8	-0.8	Return on equity (%)	-73.0%	-494.3%	66.7%	NM	111.9%										
Investments	0.0	0.0	0.0	0.0	0.0	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A										
Investments in intangible assets	0.0	-0.4	-0.2	-0.4	-0.4	Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%										
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	Liquidity and leverage ratios															
Investing cashflow	-1.4	-0.7	-0.9	-1.2	-1.2	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Change in borrowings	-1.4	-1.5	-1.6	-1.6	-1.7	Net debt (cash) (A\$m)	-29.1	-12.3	-20.0	-12.9	-6.0										
Equity issued	0.0	0.0	0.0	0.0	0.0	Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A										
Dividends paid	0.0	0.0	0.0	0.0	0.0	Net interest cover (x)	N/A	N/A	N/A	N/A	N/A										
Other financing cash flow	-0.3	-0.2	-0.5	-0.4	-0.4	Current ratio (x)	4.2	2.7	4.6	2.9	1.9										
Financing cashflow	-1.7	-1.7	-2.0	-2.0	-2.0	Segmentals															
Net change in cash	-15.1	-17.7	6.8	-8.2	-8.2	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Cash at end of period*	39.2	21.5	28.3	20.1	11.8	Bronchitol and Aridol															
<small>* Includes effect of exchange rate fluctuations on cash balance</small>						Product Sales	6.1	4.8	6.1	6.8	7.3										
Free cash flow (op. CF less capex and intangibles)	-13.4	-16.0	8.8	-6.2	-6.2	Other revenue (Clinical trial cost reimbursement)	8.2	8.6	1.2	0.0	0.0										
Balance sheet						Other income	0.6	0.1	0.2	0.0	0.0										
Y/e June 30 (A\$m)	2016A	2017A	2018E	2019E	2020E	Total Revenues	14.9	13.5	7.5	6.8	7.3										
Cash	39.2	21.5	28.3	20.1	11.8	EBITDA	-8.2	-7.1	-3.5	-3.7	-3.4										
Current receivables	4.8	4.4	1.4	1.5	1.6	New Drug Development															
Inventories	2.2	2.6	2.9	3.0	3.1	Product Sales	0.0	0.0	0.0	0.0	0.0										
Other current assets	0.1	0.1	0.3	0.3	0.3	Other revenue (Milestone+license+royalty)	0.0	0.0	42.1	10.8	7.9										
Current assets	46.4	28.6	32.9	24.9	16.8	Other income (R&D tax incentive etc.)	2.6	3.4	0.2	0.2	0.2										
PPE	17.8	14.9	12.3	9.7	7.0	Total Revenues	2.6	3.4	42.3	10.9	8.1										
Non-current receivables	1.3	1.4	1.5	1.5	1.5	EBITDA	-2.6	-4.1	27.3	1.3	2.2										
Intangible assets	0.1	0.5	0.6	1.0	1.3	Corporate															
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Other income	0.3	0.3	0.5	0.5	0.5										
Non-current assets	19.2	16.8	14.5	12.2	9.8	EBITDA	-4.0	-4.0	-13.6	-4.2	-4.2										
Total assets	65.7	45.4	47.3	37.0	26.7	Total Company															
Payables	5.0	6.8	4.3	5.4	5.5	Revenues	17.8	17.3	50.2	18.2	15.8										
Debt	10.1	9.3	8.3	7.1	5.9	EBITDA	-14.8	-15.2	10.2	-6.6	-5.4										
Provisions	0.8	0.9	1.0	1.1	1.2	Interims															
Financial liabilities (Novaquest financing agreement)	23.2	22.1	21.7	21.3	20.9	Y/e June 30 (A\$m)	2H16A	1H17A	2H17A	1H18A	2H18E										
Deferred Lease Incentive	1.9	1.6	1.4	1.1	0.9	Revenue	9.1	6.5	10.8	31.1	19.1										
Other liabilities	3.7	1.1	0.0	0.0	0.0	EBITDA	-6.8	-8.4	-6.8	7.8	2.4										
Total liabilities	44.7	41.9	36.7	36.1	34.4	Depreciation & Amortisation	-1.5	-1.5	-1.5	-1.6	-1.6										
Net Assets	20.9	3.5	10.6	0.9	-7.7	EBIT	-8.3	-10.0	-8.3	6.2	0.8										
Shareholders' equity	344.6	344.6	344.6	344.6	344.6	Net interest & Other Expense	3.6	-0.6	1.5	0.3	-0.3										
Reserves	18.6	19.5	20.7	21.9	23.1	Pre-tax profit	-4.7	-10.6	-6.8	6.5	0.6										
Retained earnings/(losses)	-342.3	-360.6	-354.8	-365.6	-375.5	Tax	0.0	0.0	0.0	0.0	0.0										
Total shareholders equity	20.9	3.5	10.6	0.9	-7.7	Net Profit (loss) - normalised	-4.7	-10.6	-6.8	6.5	0.6										
						Net Profit (loss) - reported	-5.3	-11.0	-7.3	5.9	-0.1										

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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